VDD MICRA TPS

MARVEL *feasibility study*

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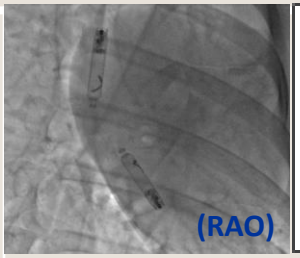
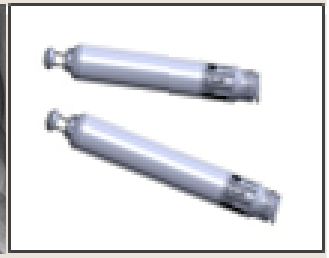
Possibilities with Leadless Technology

Applications of leadless technology

Dual Chamber Nanostim	▪ 2 Discrete devices: Right Atrium and Right Ventricle ▪ Beat to Beat Communication ▪ Chronically retrievable
Leadless ICD/PM	▪ Leadless ICD system with device-to-device communication to Nanostim ▪ Nanostim device paces, senses, and delivers ATP therapy
Leadless CRT	▪ Evaluate leadless options for CRT therapy delivery ▪ Applicable to low and high voltage
Pediatric Leadless	▪ Miniaturize present leadless pacemaker ▪ Fully retrievable ▪ Reduce complications from venous adhesions

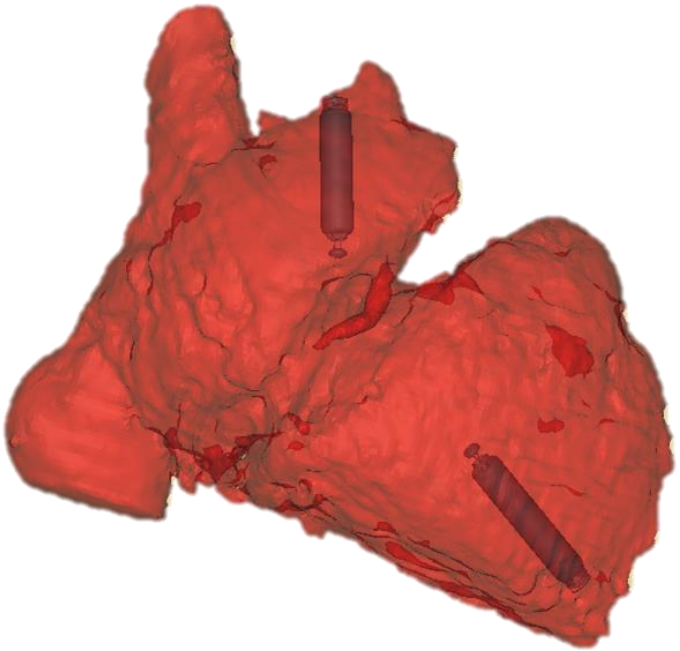




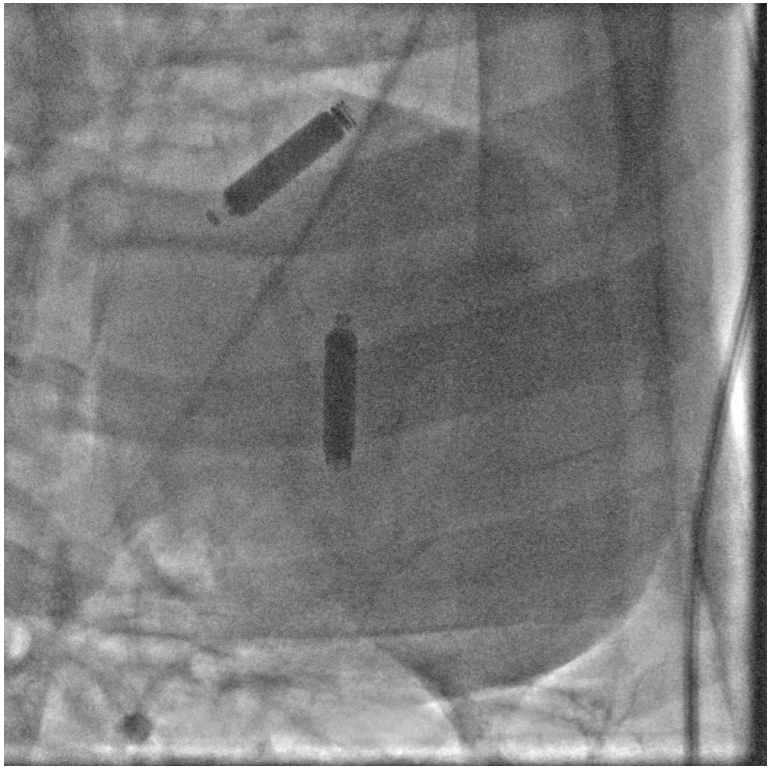
Leadless Dual Chamber Pacemaker

Develop leadless dual chamber pacemakers that:

- *Can be safely implanted into the RA and RV*
- *Beat-to-beat communication with an AV delay*
- *Provide dual chamber functionality similar to that of conventional DDD PM*
- *Retrievable and upgradeable*



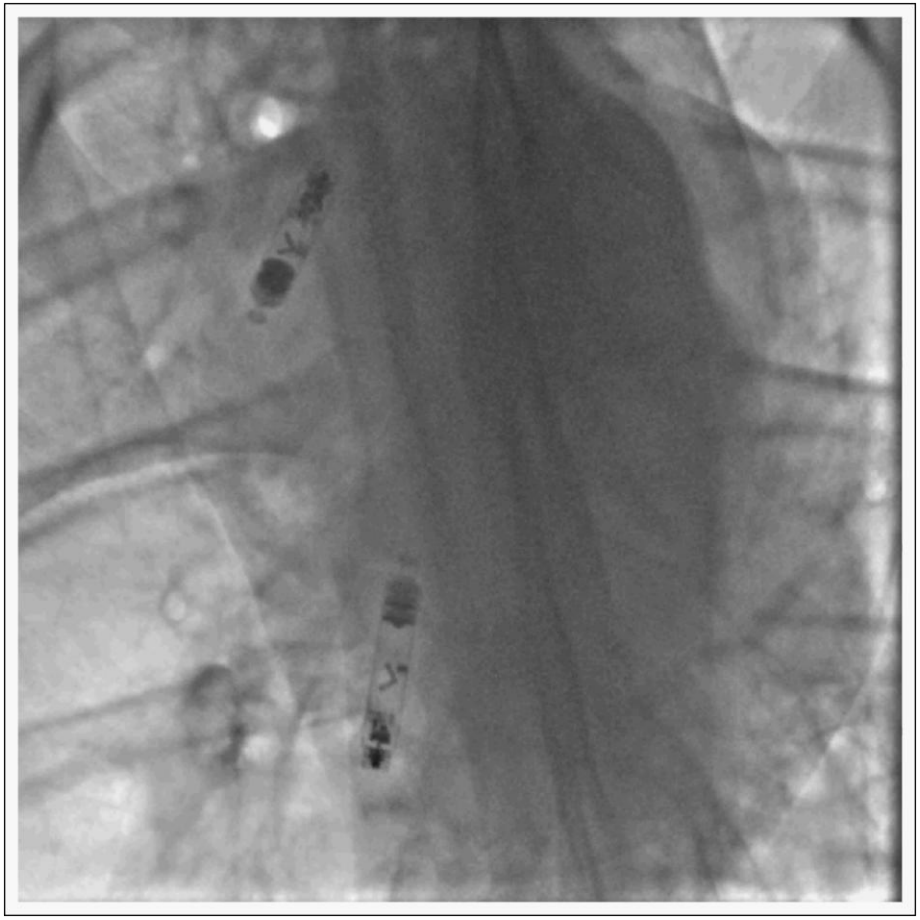
Human Heart Volume Model

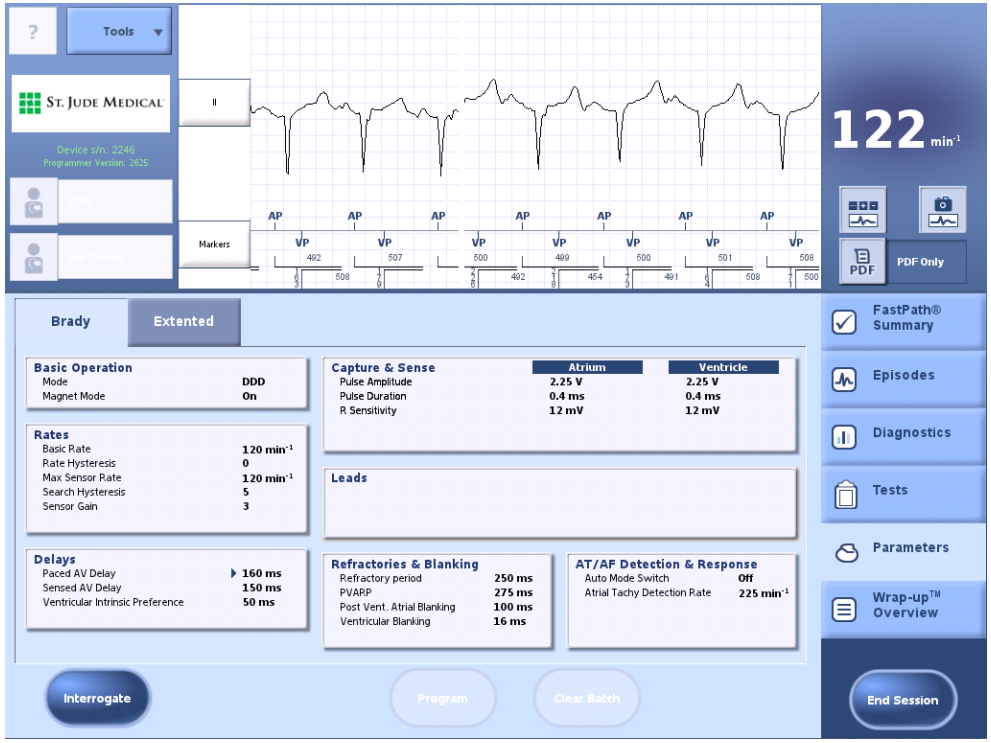


Dual Chamber Implant, Ovine

Nanostim Dual Chamber Leadless System

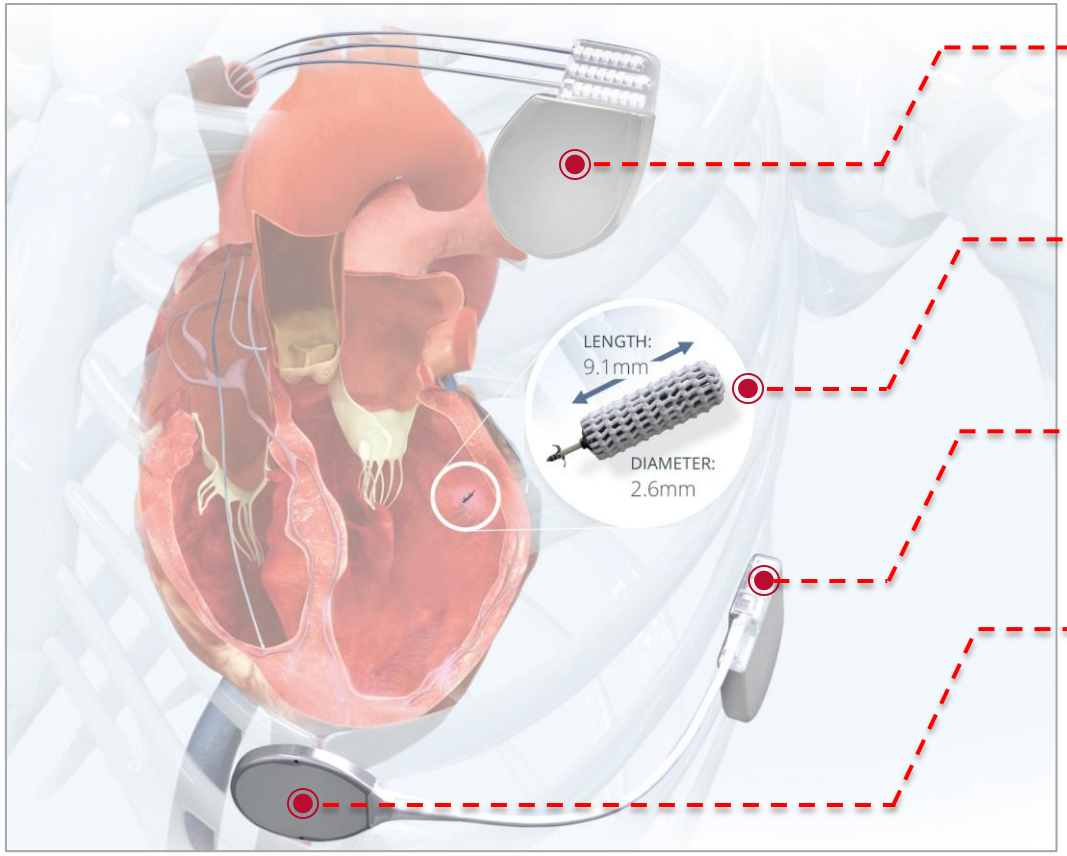
Pre-clinical Studies — In-Vivo Implantation





Ovine Pre-clinical implant

WiCS – ultrasound powered CRT
Implanted System Principle



CO-IMPLANT DEVICE
Co-implanted pacemaker, ICD or CRT paces the right ventricle.

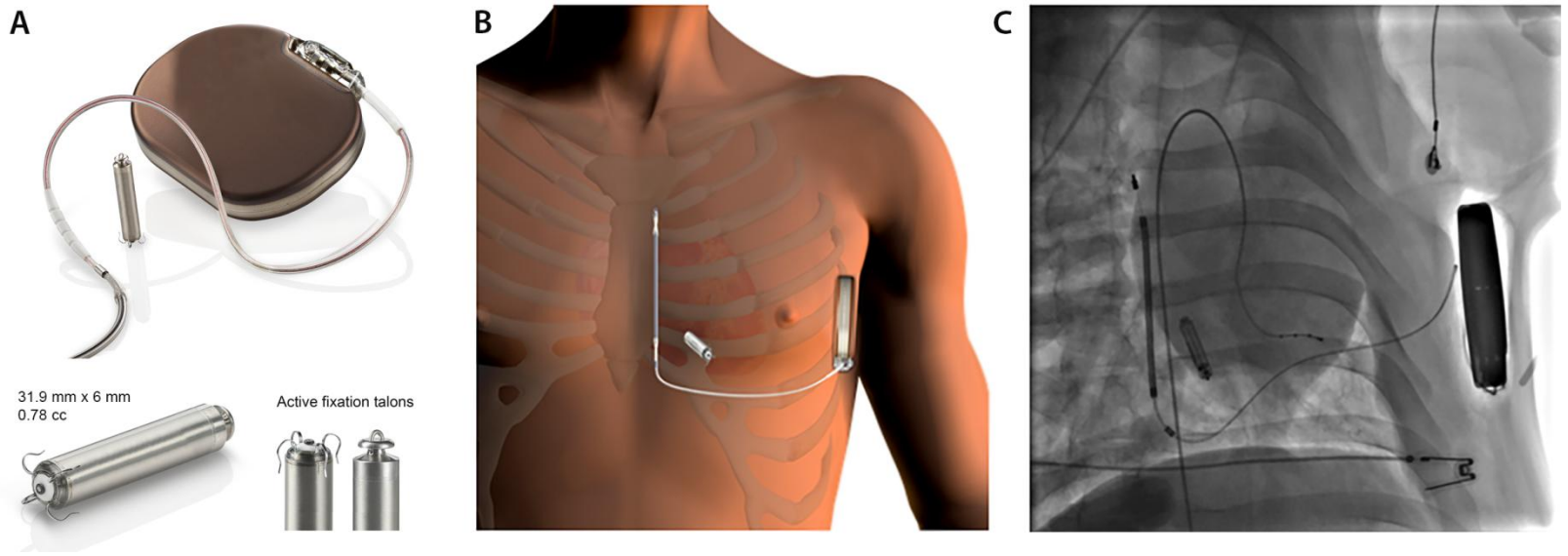
RECEIVER ELECTRODE
Implanted onto the endocardium, the receiver electrode converts ultrasound energy into electrical energy to pace the left ventricle.

BATTERY
Implanted subcutaneously on the left mid axillary line, powers the transmitter.

TRANSMITTER
Phased array ultrasound transmitter is implanted sub-muscular over a cardiac echo window. Synchronizes with an RV pacing pulse to transmit ultrasound energy to the receiver electrode to provide Bi-V endocardial pacing.

Acute & 3-months Performance of a Communicating Leadless ATP Pacemaker & S-ICD: ***pre-clinical model***

Concept: Leadless System Delivers Pacing, ATP, and Defibrillation

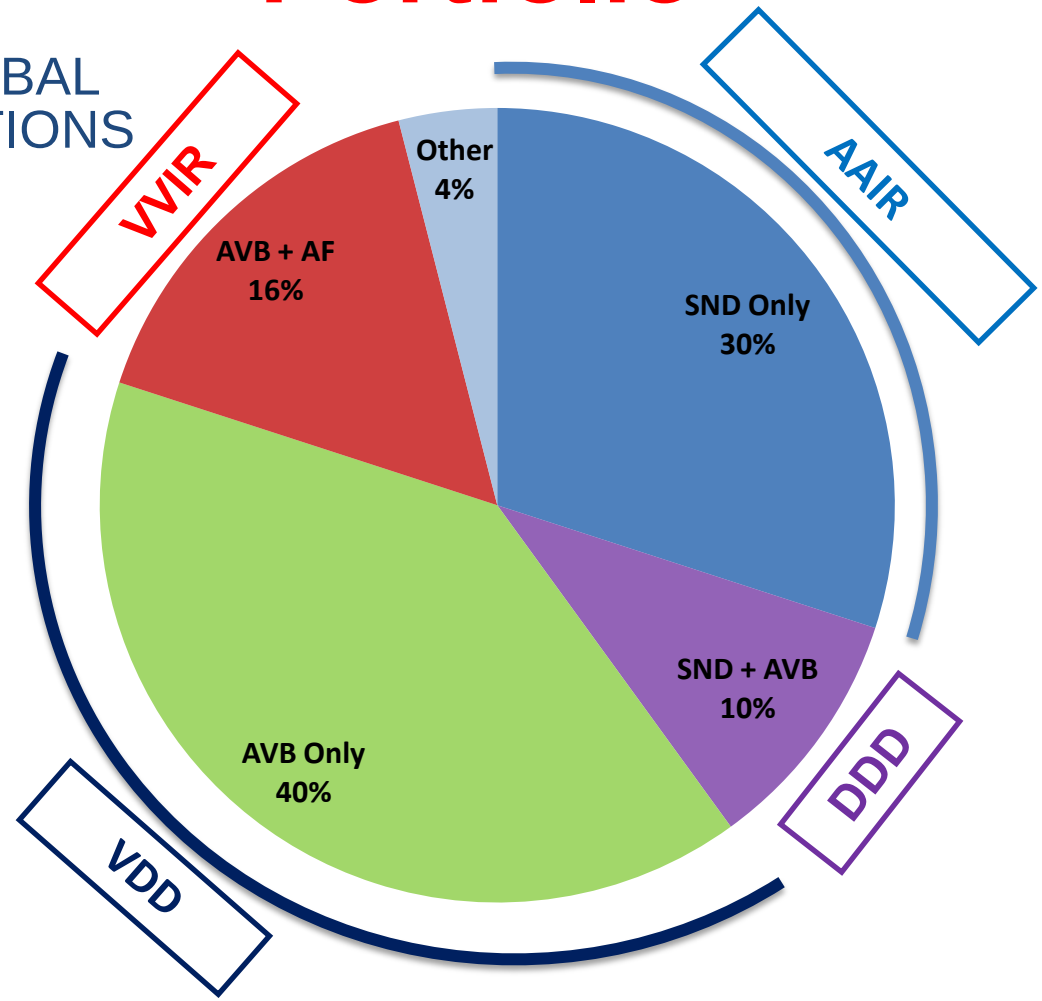


Concept device, Not approved & not available for sale

Tjong F.V.Y. et. al., JACC:CE,,Article in Press

Significant Opportunity for Micra Portfolio

BASED ON GLOBAL BRADY INDICATIONS



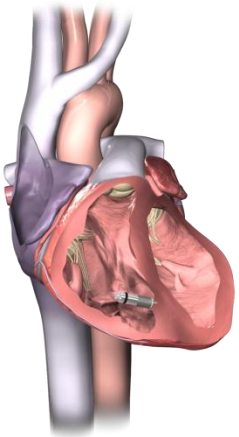
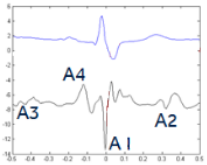
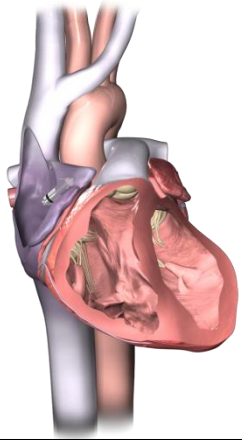
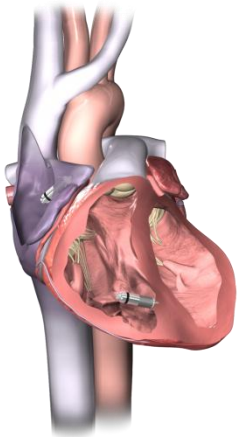
Indication Data

*__Other__ includes (unexplained) syncope, (bradycardia due to) atrial fibrillation, supraventricular arrhythmia

Based on PANORAMA, SavePace, MOST, OPTI-MIND, ESC Country & US Registries

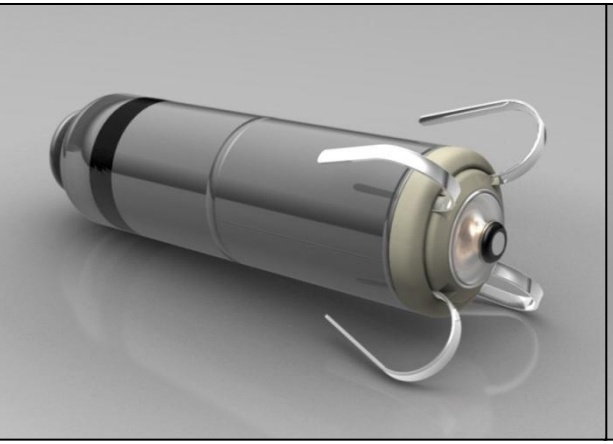
Next Generation Micra

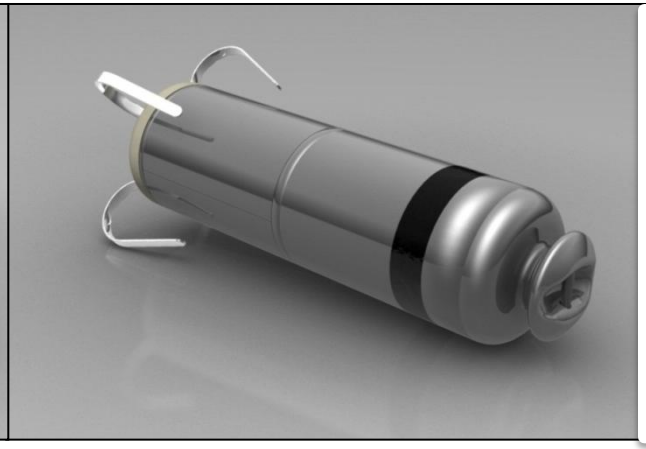
**BEGIN WITH MICRA AVS, FOLLOWED BY MICRA AAIR,
TO COMPLETE MICRA DDD SYSTEM**

Pacing Mode	VDD →	AAIR →	DDD
	 +   = 		
Description	• Sense atrial contractions from the ventricle • Pacing in the V	• Sense & pace right atrium • AT/AF diagnostics • AVI monitoring for AVB	• Sense atrial contractions from the ventricle • R-wave sensing in atrium • Pacing in A & V
Indication	AV block with normal sinus node function	Sinus node dysfunction	Sinus node dysfunction with AV conduction disturbance

TPS Micra ™ Device

od VVI k VDD





- KS režim: VVIR- VDD(R)
- Objem identický : 0.75ml
- Hmotnost: 2g
- Délka: 24mm
- Šířka: 20Fr
- Bipolární stimulace (17mm)

Micra Atrial TRacking Using a Ventricular AccELerometer Study

NCT03157297

Cíl studie: hodnocení účinnosti MARVEL algoritmu, který je adaptován pro původní MicraTM TPS s cílem dosažení synchronní komorové stimulace u nemocných s AV blokádou vyššího stupně.

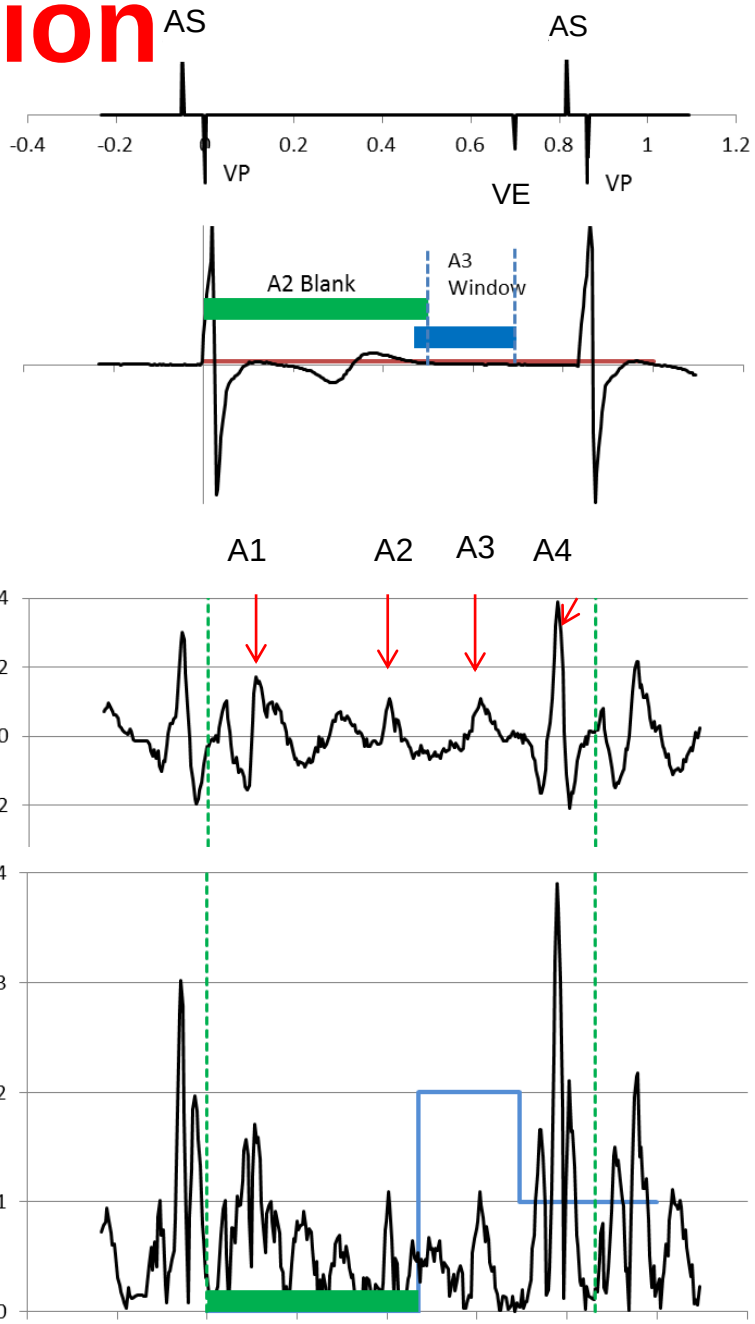
Primární cíl:

Synchronizace VVI → VDD

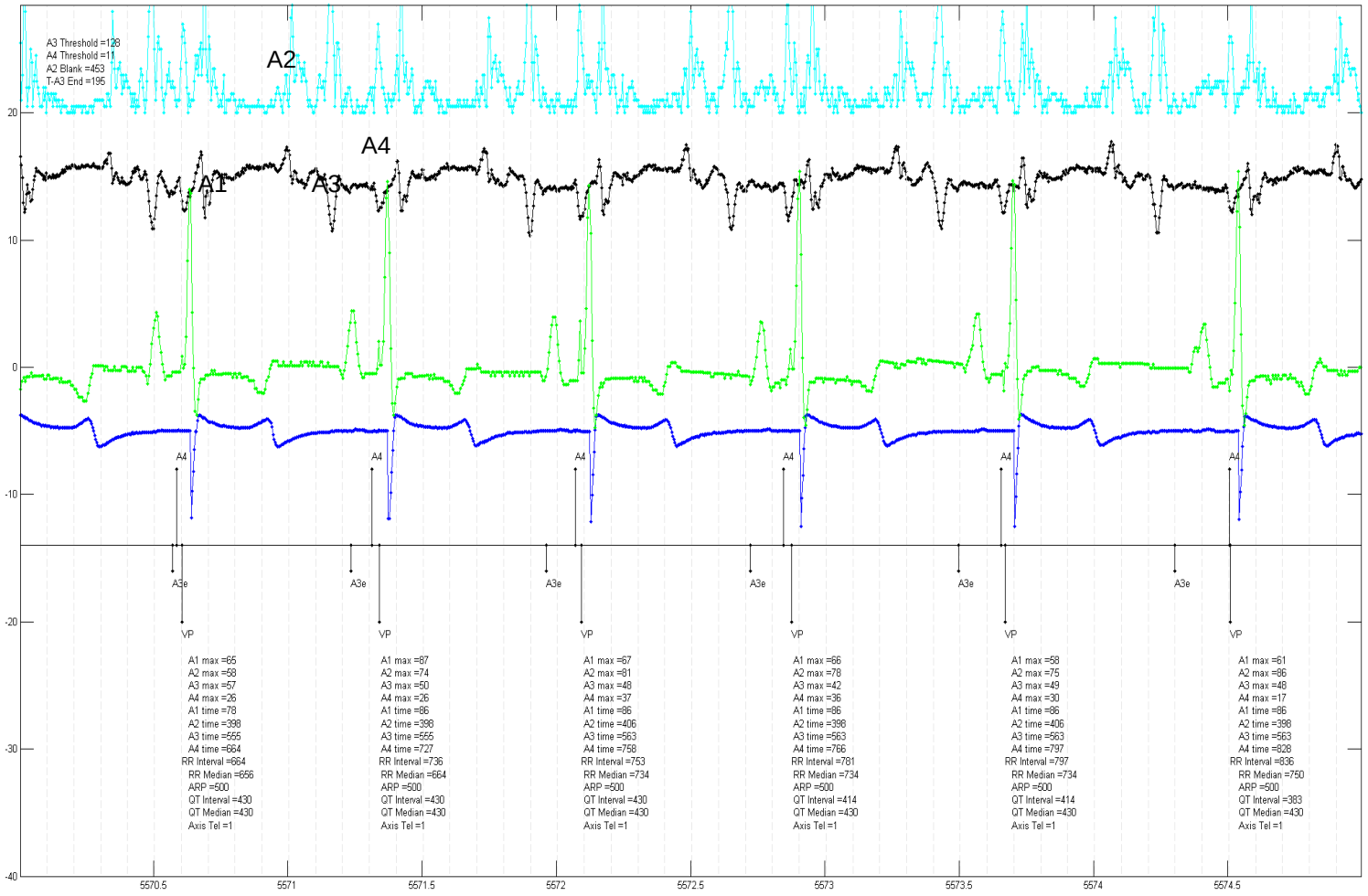
Pomocí 3 již implementovaných akcelerometrů detekuje síňovou aktivitu na základě pohybu cípů trojcípé chlopně - v souhlase s detekcí P-vlny.

Algorithm Description

- High pass filter accelerometer (5-10Hz)
- Rectify filtered accelerometer
- Blanking after ventricular sense
- Blanking or increased threshold after T-wave to blank A3
  - Measurements in hardware, blanking set by firmware
- Detect A4 as first crossing of threshold of rectified, filtered accelerometer
  - Typically 0.10-0.15g



MARVEL PROVIDING AV SYNCHRONY IN AV BLOCKED PORCINE



RESEARCH SYSTEM

2090 with MARVEL Software

2090 injects Micra with MARVEL RAMware

Tel-B

Micra with MARVEL RAMware

Holter continuously uplinks data

Tel-B

ER220 Holter Recorder

+

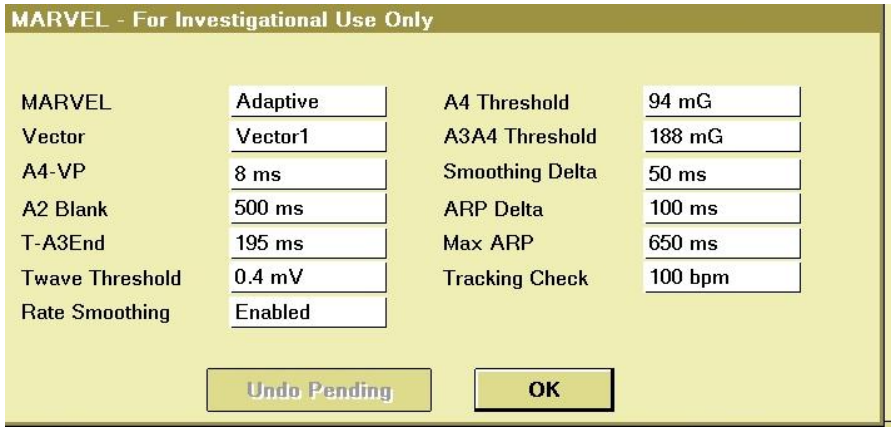
Activity Monitor (Accelerometer) (ActiGraph)

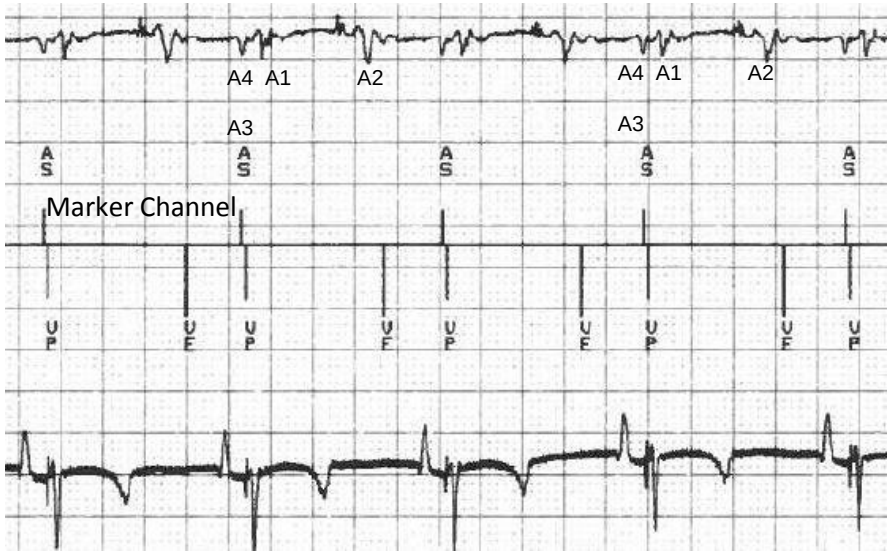
SDN

MARVEL Software distributed via SDN

Optimization phase

ADJUSTING PARAMETERS DETAILS



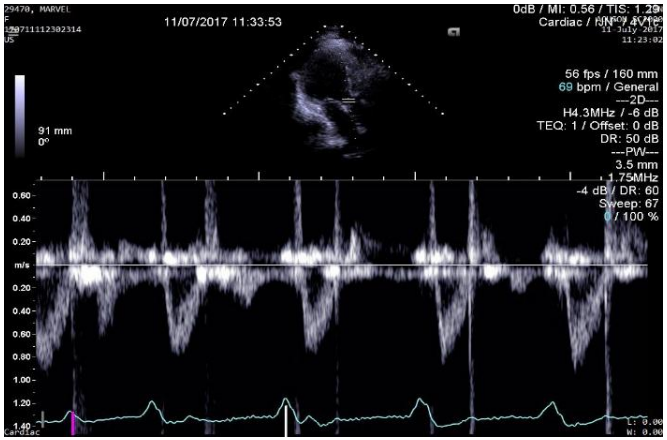


AV blocked pig with AV synchrony restored with MARVEL

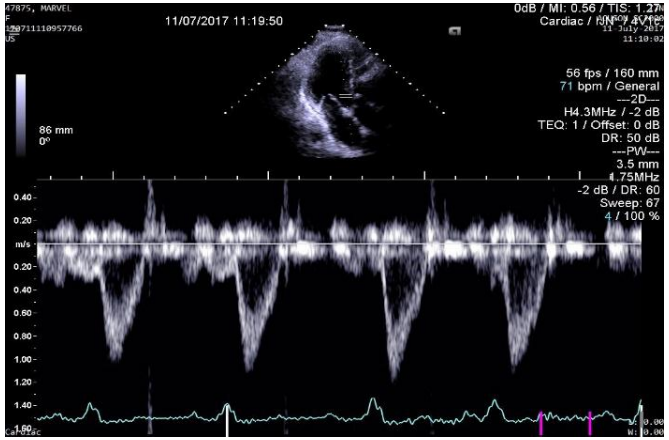
- MARVEL includes two new markers:
  - AS for when A4 detected.
  - VE for when algorithm expects no more ventricular related accelerometer signals.
  - Accelerometer waveform signal is provided
- Adjust VE marker
  - T-wave end + T-A3 end
  - Should be adjusted beyond A3 signal.
- Detect A4 (AS)
  - Adjust A4 threshold to detect A4 without detecting end of A3

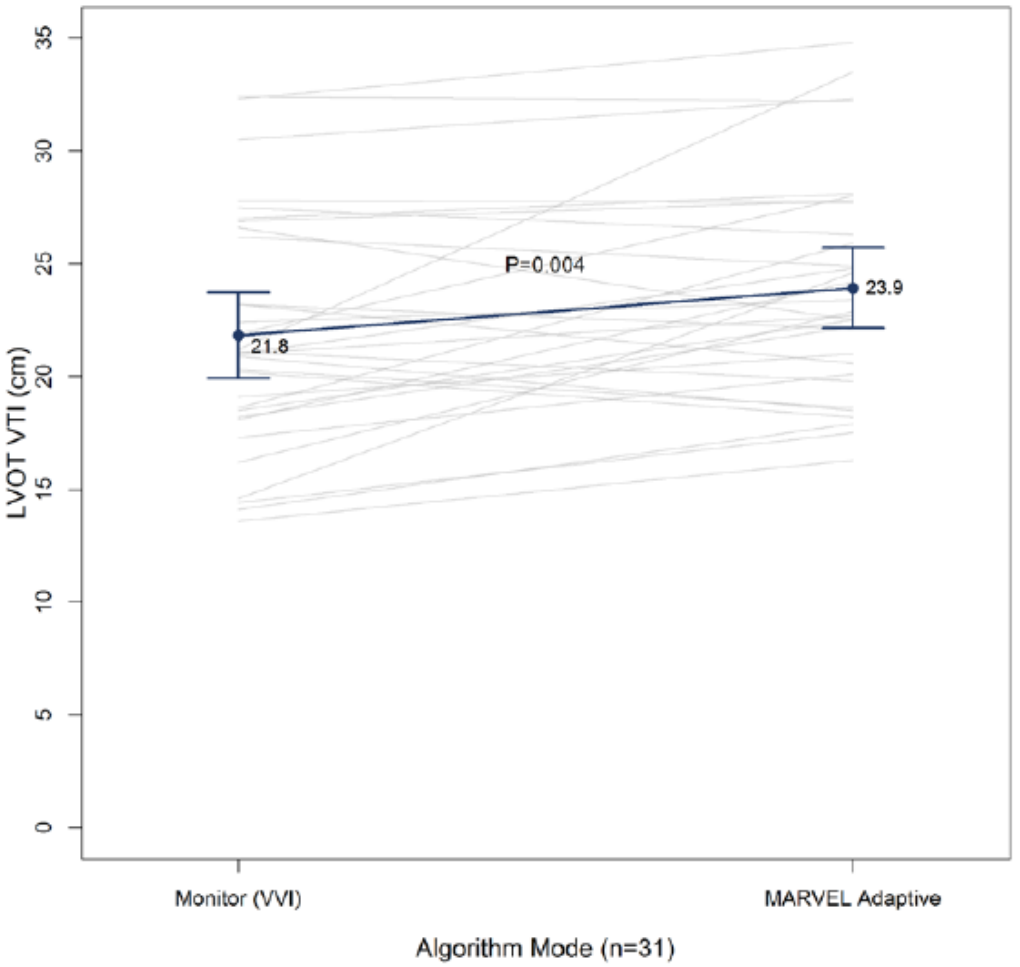
Results *Comparison VVI and Marvel adaptive*

VVI stimulace



VDD stimulace MARVEL





Results

- A total of 64 patients completed the MARVEL study procedure at 12 centers in 9 countries.
- Patients were implanted with a Micra for a median of 6.0 months (range: 0–41.4).

- a) High-degree AV block: 33 pts
  b) Predominantly intrinsic rhythm: 31 pts

- Average AVS during AV algorithm pacing was **87.0%** ***(CI: 81.8%- 90.9%);***
  → **80.0%** in high-degree block pts and
  94.4% in pts with intrinsic conduction.

- AVS was significantly greater ***(P<0.001)*** during AV algorithm pacing compared to VVI in high degree block patients while AVS was maintained in patients with intrinsic conduction.
- Decrease AVS during physical effort (due to lowering atrial signal)
  mo effect of body position
- **In our center 6 patients (4 M/2W) were enrolled with high degree AV block in 4 and lower degree AV block in 2. In our cohort VDD response** was similar compared to all study patients.

Conclusions

- Leadless pacing can change this therapy paradigm
- Development of dual chamber pacing and/or more physiological pacing is critical
- Accelerometer-based atrial sensing is feasible and significantly improves AV synchrony in patients with AV block and a single-chamber leadless pacemaker implanted in the RV

LIMITATION OF CURRENT SYSTEM

Not possible long-term / high consuption of battery:

- Aktivation of MARVEL sofware/ 24h → shorter life spam several weeks

Time consuming manual programming:

- From10 min up to 30 min
- Potentially complicated in patients with low A4 signal to A1-A3
- Wosening of AVS in SND, VPBs and low signal amplitude

Missing data:

- Acute data showed short-term feasibility→ long-term not known
- How much % of AVS for patient clinical benefit is needed